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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,550	11/05/2003	Theo T. Nikiforov	100/07934	1067
21569	7590	07/23/2004	EXAMINER	
CALIPER LIFE SCIENCES, INC. 605 FAIRCHILD DRIVE MOUNTAIN VIEW, CA 94043-2234			CALAMITA, HEATHER	
		ART UNIT		PAPER NUMBER
				1637

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/701,550	NIKIFOROV, THEO T.
	<b>Examiner</b> Heather G. Calamita, Ph.D.	<b>Art Unit</b> 1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05 November 2003.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-9 and 17-28 is/are pending in the application.
- 4a) Of the above claim(s) 10-16 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-9 and 17-28 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-28 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 5 November 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-9 and 17-28, drawn to a method of monitoring kinase activity, classified in class 435, subclass 4.
  - II. Claims 10-16 and 17-28, drawn to a method of monitoring phosphatase activity, classified in class 435, subclass 21.

The inventions are distinct, each from the other because:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions Group I is drawn to kinases which function by transferring phosphate groups from ATP to organic molecules. Group II is drawn to phosphatases, which are a specific class of enzymes that catalyses (i.e. speeds up) the removal of phosphate groups from proteins.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Claims 17-28 link(s) inventions Group I and Group II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 17-28. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional

application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

During a telephone conversation with Don McKenna on July 8, 2004 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-9 and 17-28. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Claim Objections***

2. Claim 24 is objected to because of the following informalities: In line 1 of the claim “compriss” is misspelled. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 17-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims are broadly drawn to a genus of molecules having multivalent metal cations associated therewith which are different from those disclosed in the specification. The genus includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only the particularly named amino acids (specifically polylysine and polyarginine). Thus, applicant has express possession of only two particular molecules which are associated with multivalent cations in a genus which comprises hundreds of millions of different possibilities. Here, no common elements or attributes of the molecules are disclosed. No structural limitations or requirements which provide guidance on the identification of molecules which meet the functional limitations are provided.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the compound solely by its functional utility, as a molecule having multivalent cations associated with it, without any definition of the particular molecules claimed.

In the instant application, certain specific molecules are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any molecules having multivalent metal cations associated with them other than those expressly disclosed which comprise polylysine and polyarginine.. Therefore, the claims fail to meet the written description requirement by encompassing molecules which are not described in the specification.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-9, 17-28 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Coffin et al., *Analytical Biochemistry*, 02/15/2000.

With regard to claims 1 and 17, Coffin et al. teach measuring the activity of kinase enzyme by providing a fluorescently labeled phosphorylatable compound, a kinase enzyme and a phosphate donor group where the kinase enzyme transfers the phosphate group from the phosphate donor group to the phosphorylatable compound to make a phosphorylated product, contacting the phosphorylated product with a molecule having multivalent metal cations associated with it, and determining a level of phosphorylated product by detecting a level of fluorescence intensity emitted from the reaction mixture (see whole document, specifically p 208, col. 1, paragraph 2). With regard to claims 2 and 19, they teach

serine, tyrosine or threonine as a substrate (see p. 207 col. 2 paragraph 3 line 3). With regard to claims 3 and 20, they teach the multivalent metal cations bind the molecule to the phosphorylated product partially due to charge difference between the phosphorylated product and the multivalent metal cation (see p. 211 paragraph 2 lines 9-14). With regard to claims 4 and 21, they teach the multivalent metal cations bind the molecule to the phosphorylated product partially due to specific binding affinity between the phosphorylated product and the multivalent metal cation (see p. 209 col. 1 paragraph 1). With regard to claim 7, they teach introducing at least a first test compound to the reaction mixture and comparing the level of fluorescent intensity emitted from the reaction mixture in the presence of the test compound to the level of fluorescent intensity emitted from the reaction in the absence of the test compound (see p. 208, col. 1 paragraph 2). With regard to claim 8, they teach repeating the steps of introducing and comparing with a plurality of different test compounds (see p. 208, col. 1 paragraph 2). With regard to claim 9, they teach the molecule comprises a polymer (see p. 208, col. 2 line 10). With regard to claim 18, they teach the enzyme modifying the chemical structure of the substrate by addition to, subtraction from, or alteration of its chemical structure (p. 208, col. 1 paragraph 1). With regard to claim 24, they teach the substrate as phosphorylated and the enzyme is a phosphatase enzyme (see p. 212, col. 1 paragraph 3). With regard to claim 27, they teach using fluorescence polarization detection (see p. 207 col. 1 paragraph 1). With regard to claim 28, they teach fluorescence intensity detection (see p. 207 col. 1 paragraph 1).

### ***Summary***

5. No claims were allowed.

### ***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita, Ph.D. whose telephone number is 571.272.2876 and whose e-mail

address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday thru Thursday 7:00 A.M. - 5:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571.272.0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

hgc

  
JEFFREY FREDMAN  
PRIMARY EXAMINER  
